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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,112	03/23/2006	Wolfgang Haigis	3795.05WOUS	8743

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EXAMINER

SHIPMON, TIFFANY P

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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01/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,112	Applicant(s) HAIGIS, WOLFGANG	
	Examiner TIFFANY SHIPMON	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-19 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-19 and 21-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 8/17/2009 have been fully considered but they are not persuasive. Applicant's representative argues that the method of Rosa is purely theoretical and is not based on any physical measurement of the eye, for example, without any measuring instrument. Examiner asserts that Rosa discloses that an eye length measurement was taken using an IOL Master (page 720, col. 2 paragraph, 5). Therefore applicant's arguments are not persuasive.
2. In response to applicant's arguments, the recitation "implemented by the measuring instrument" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Therefore the independent claims are still non-statutory because it does not result in any transformation.

Specification

The amendment filed 8/17/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

page 4 of the specification adds the new matter as follows: "Other measuring instruments known to those of skill in the art include ophthalmometer, keratographer, Anterior Segment OCT (ocular coherence tomography) instruments, Pentacam, Orbscan and others".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-19 and 21-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to another statutory class (such as a particular machine). See *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Bilski* (Fed Cir, 2007-1130, 10/30/2008)) where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101. The claimed subject matter does not

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require a machine to manufacture or calculate the intraocular lens (IOL) nor does it produce a physical transformation. Furthermore, the instrument does not place a meaningful limit on the method because it is not clearly utilized in the actual method steps.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-19, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosa ("A New Method of Calculating Intraocular Lens Power After Photorefractive Keratectomy"). Referring to claims 6 and 21, Rosa discloses a method for determining pre-refractive intervention corneal refractive powers and post-refractive intervention corneal refractive powers and utilizing determined values for pre-refractive intervention corneal refractive powers and post refractive intervention corneal refractive powers to calculate the parameters of an optimally adapted intraocular lens (page 721, col. 1 paragraph 4). Rosa discloses using an IOL Master (measuring instrument) to obtain axial eye length measurement (page 720, col. 2 paragraph 5). Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to

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modify the method of Rosa to obtain all of the pre-refractive intervention corneal refractive powers and post-refractive intervention corneal refractive powers using a measuring instrument in order to obtain accurate measurements.

6. Referring to claims 7-8, and 22-23, Rosa discloses calculating the corneal radius and then calculating a ratio between the calculated and measured postoperative radius is disclosed on page 721 column 2, lines 2-7. Rosa does not disclose measuring a first anterior and first posterior corneal radius before the refractive intervention; where determining the corneal refractive powers before intervention comprises deriving a first anterior corneal radius from a first posterior corneal radius from a second anterior and second posterior radius measured after the refractive intervention. If the postoperative radius was measured after the refractive intervention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Rosa, to derive and obtain a first anterior and first posterior corneal radius when the post operative data is present in order to correlate the axial length for calculating the IOL power after surgery.

7. Referring to claims 9 and 24, Rosa discloses taking into account the parameters of the measuring instrument used for measuring the second anterior and second posterior corneal radius measured after the refractive intervention as shown in Table 1 on page 722 of Rosa.

8. Referring to claims 10 and 25, Rosa discloses that the parameters of the measuring instrument taken into account comprise a keratometer refractive index on page 721, column 2, lines 2-4.

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9. Referring to claims 11 and 26, Rosa discloses measuring to determine measured values and applying a correction value to the measured values on page 721 column 2 lines 13-14 and page 722 lines 1-6.

10. Referring to claims 12 and 27, Rosa discloses that the IOL power found before surgery yields the same results as using the mean post-operative corneal radii measurements on page 720 column 1 lines 9-15. Rosa does not disclose deriving the post refractive corneal radii from the preoperative corneal radii; however it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the pre-refractive corneal radii from the IOL powers obtained before the intervention, to determine the post refractive corneal radii.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. –US Patent No. 7,476,248 -US Patent No. 5,092,880 –US Patent No. 6,634,751 -US 2002/0103479 –US 2003/0053025 –US 20050073647 -US Patent No. 5282852 -US Patent No. 6626538 –US Patent No. 6634751 –US Patent No. 7,476,248 and -US Patent No. 7,490,938 all discloses determining the value of power in an IOL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY SHIPMON whose telephone

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number is (571)270-1448. The examiner can normally be reached on Monday thru Friday, 8AM-5 PM, Est., alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul Prebilic/
Primary Examiner, Art Unit 3774

/T. S./
Examiner, Art Unit 3738